

Form PTO-1390 (REV 10-95)		U.S. Department of Commerce Patent and Trademark Office	ATTORNEY'S DOCKET NUMBER ORTHO-A-CIP-PCT. US 10/089040
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/089040
INTERNATIONAL APPLICATION NO. PCT/US96/13570	INTERNATIONAL FILING DATE 19 August 1996	PRIORITY DATE CLAIMED 23 August 1995	
TITLE OF INVENTION: Open Helical Organic Tissue Anchor and Method of Facilitating Healing			
APPLICANT(S) FOR DO/EO/US Ortho Helix Limited/ Kay, David B.			

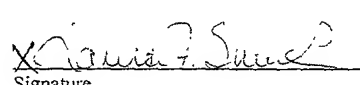
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2))
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:

Express Mail Certificate
 Verified Statement Claiming Small Entity Status
 Rule 34 Amendment

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/089048		PCT/US96/13570		ORTHO-A-CIP-PCT.US	
10/089048				CALCULATIONS PTO USE ONLY	
17. <input checked="" type="checkbox"/> The following fees are submitted:					
BASIC NATIONAL FEE (37 CFR 1.492 (A) (1)-(5):					
Search Report has been prepared by the EPO or JPO \$880.00					
International preliminary examination fee paid to USPTO (37 CFR 1.482) \$680.00					
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) \$770.00					
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$1010.00					
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) \$96.00					
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$ 96.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)).				20 <input type="checkbox"/> 30 <input type="checkbox"/>	\$
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	18 -20 =		X\$	\$	
Independent claims	5 -3 =		X\$80.00	\$ 160.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+\$250.00	\$ -0-	
TOTAL OF ABOVE CALCULATIONS =				\$ 256.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37CFR 1.9, 1.27, 1.28)				\$ 128.00	
SUBTOTAL =				\$ 128.00	
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492(f)).				20 <input type="checkbox"/> 30 <input type="checkbox"/> +	\$ -0-
TOTAL NATIONAL FEE =				\$ 128.00	
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
TOTAL FEES ENCLOSED =				\$ 128.00	
				Amount to be refunded:	\$
				Charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ 128.00 to cover the above fees is enclosed.					
b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit No. 08-3150. A duplicate copy of this sheet is enclosed.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO:					
Laura F. Shunk, Esq. Hudak & Shunk Co, L.P.A. 7 West Bowery Street, Suite 808 Akron, Ohio 44308-1133 (330) 535-2220					
 Signature Laura F. Shunk Name 31.423 Registration Number					

Applicant or Patentee: David B. Kay
Serial or Patent No.: _____
Filed or Issued: _____

Attorney's
Docket No.: ORTHO-A

Title: OPEN HELICAL ORGANIC TISSUE ANCHOR
AND METHOD OF FACILITATING HEALING

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office regarding the invention entitled OPEN HELICAL ORGANIC TISSUE described in: ANCHOR AND METHOD OF FACILITATING HEALING

☒ the specification filed herewith.

☐ application serial number _____, filed _____
☐ patent number _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:*

☒ No such person, concern, or organization
☐ Persons, concerns or organizations listed below*

* Note: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME _____
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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

David B. Kay
NAME OF INVENTOR
David B. Kay
Signature of inventor
8-23-95
Date

NAME OF INVENTOR

Signature of inventor

Date

NAME OF INVENTOR

Signature of inventor

Date

OPEN HELICAL ORGANIC TISSUE ANCHOR
AND METHOD OF FACILITATING HEALING

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FIELD OF INVENTION

5 The present invention relates to tissue anchors as well as to methods of promoting healing or repairing hard or soft, living, organic tissue using an open helix anchor.

BACKGROUND OF THE INVENTION

10 The present invention relates to an anchor (or connector) which can be used to fasten organic tissue in close proximity in order to afford the tissue the opportunity to heal. The anchor of the present invention can be
15 used to anchor and clamp dense, regular and/or dense, irregular connective tissue in place in relation to bone. The anchor can also be used for cartilage transplants, i.e., for holding cartilage in fixed relation to bone, and can also be used in bone as a buttress, such as for
20 buttress plating techniques, or to fasten pieces of bone together as a screw substitute.

 As compared to the prior art, the anchor of the present invention allows a method of holding together organic tissue with minimal disruption to the biological
25 environment or to the tissue itself. For example, prior art devices and methods customarily require a large hole for insertion of the anchoring device, causing not only structural damage to the implantation site, but also inflicting further trauma to the biological site such as
30 generating heat, introducing further possibility for infection, and destroying bone which may be needed to help heal the repaired area. Such trauma is amplified in cases where prior art devices malfunction during the implant procedure. Hooks or screws can get stuck and further
35 obscure the operating site or require tedious removal.

 The anchor of the present invention may be very useful for applications such as anchoring ligaments or tendons when performing soft tissue surgical reconstruction, ruptured tendons, or torn ligaments, in which the

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surgeon wants to reconstruct or repair connective tissue with respect to the bone.

The anchoring device functions to hold together the tissue (such as connective tissue to bone) for a relatively limited time frame, e.g., six to twenty-six weeks, during which time the biological system will heal.

The anchor of the present invention can be used with advantage in many of the same applications in which cancellous screws are used in addition to applications in which traditional prior art anchoring techniques are unsatisfactory. The anchor of the present invention is far less invasive to implant than cancellous screws or hook-style anchors, i.e., the implant has a minimized mass, the insertion point is small relative to the size of the implant, and the device involves minimal removal of native tissue. In addition, the area of bone which is needed to secure the present invention can be of poorer quality than for prior art devices.

Additionally, the anchor of the present invention can be removed and minimally reangulated in order to utilize the same surgical site. Prior art devices require a large hole (relative to implant size) to be drilled in order to implant the device, and once the hole is contaminated by malfunction or misalignment of the device, it is necessary to drill another hole far enough away to achieve stability in a new location. Given the surgical context, this is extremely inconvenient.

The anchor of the present invention can be used in methods of ligament, tendon, or other tissue repair. For example, the anchor can be used for a method involving cartilage transplant and it can be used alone or in conjunction with a plate for a method of buttressing bone where the quality of bone may be questionable due to trauma or degenerative disease. The anchor may be used in methods of fixation involving connective tissue repair and replacement and may be inserted using a plunge-handle or

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"T" handle inserter which utilizes longitudinal travel in order to achieve rotational insertion.

Specifically, the anchor is used in ligament or tendon repair in which a pilot hole, having a diameter
5 much smaller than the outer diameter of the helical anchor, is drilled in the cortex of the bone. The angle of implantation can be varied as necessary. The anchor is subsequently mounted or loaded into the insertion tool, threaded into the pilot hole, and screwed into the bone an
10 appropriate distance so that the anchor head can be accessed but is not obtrusive. The ligament or tendon is attached to the anchor, such as by suturing.

In addition, the anchor of the present invention can be used to anchor plates and is particularly useful in
15 instances where the bone is of poor quality. In one embodiment, a modular head is used. A particularly desirable head has an internal hex slot to permit the anchor to be implanted. In addition, the head has a transverse through slot to hold a suture. The head has a
20 low, rounded profile with a distal stem which fits inside a ring of the helix and is laser-welded thereto.

SUMMARY OF THE INVENTION

The anchor in accordance with the invention
25 comprises an open helical structure which is a constant or varied-diameter, elongate member, fiber, or filament comprised of a relatively rigid, biocompatible material such as a wire having a diameter which may vary optimally from about 0.2 millimeters to about 5.0 millimeters. The
30 length of the anchor will depend upon the particular application, but will range generally from about 3.0 millimeters to about 75.0 millimeters with the upper ranges being useful for buttressing techniques. The outer diameter of the helix will also vary in accordance with
35 the application, but it will range generally from about 1.5 millimeters to about 15.0 millimeters. A suitable rate of slope for the helix is from about 0.5 to about 10

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turns per centimeter. The aspect ratio of the helix, which as used herein means the ratio of the helix outer diameter to the fiber diameter; is an important ratio in order to achieve the proper stiffness to enable insertion and to firmly seat in the bone; a suitable range is 3.5 to 4.5.

Advantageously, the anchor of the present invention involves relatively simple, cost-effective manufacturing processes. The present anchor is also less intimidating to doctors and patients than prior art devices and can be used with simple, straight-forward instrumentation. Finally, since the device is relatively noninvasive, several can advantageously be used together in instances where more than one prior art device could not be used. It is preferred, but not necessary, that the helix has a constant circular diameter and a constant slope (meaning the rate of turn per unit of longitudinal length).

For its connective applications, the anchor includes an attachment head at one end which is suitable for securing the tissue or suture which is to be held. For example, in the case of a filamentary anchor, the anchor may have a hook, crossbar or eyelet. For applications in which the anchor secures rigid material such as cartilage or a buttressing plate, the head may have a surface which is designed to distribute the load evenly over the rigid material.

In a second embodiment, the anchor will have a modular head. For example, the helical anchoring portion may terminate at the superficial end in a post that will accommodate one of several head options. These head options may include a button, clamp, clip, snap, or rivet. At the other end, the anchor includes a cutting or self-tapping point.

In accordance with another embodiment of the invention, a buttressing system is provided which compris-

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es a plate having at least two through bores which are each engaged by an open-helix anchor.

In accordance with a method of the present invention, an anchoring site is surgically accessed, the
5 helical anchor is screwed into the anchoring site, and connective tissue is secured to the attachment head of the anchor.

In accordance with another method of the invention, a bone is buttressed by surgically accessing an
10 implant site, aligning a plate having at least one aperture over the site, and securing the plate to the implant site by inserting an open-helix anchor through the aperture and into the implant site to anchor the plate with respect to the implant site.

15

DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view of the anchor device showing the attachment head in side elevation;

FIGURE 2 is a top view taken of FIGURE 1;

20 FIGURE 3 is an elevational view, similar to FIGURE 1, but showing the anchor rotated 90° to the right so that the attachment head is seen in an end view;

FIGURE 4 illustrates the pilot hole in the bone prior to insertion of the anchor;

25 FIGURE 5 illustrates an anchor in place in the cancellous portion of the bone with the attachment head projecting above the surface of the bone in order to allow attachment of the soft tissue to the anchor;

30 FIGURES 6 and 7 illustrate the tool which may be used for inserting the anchor;

FIGURE 8 is a cross-section of a second embodiment of the anchor having a modular head; and

FIGURE 9 is a top view of the head illustrating the slot in phantom.

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DETAILED DESCRIPTION OF THE INVENTION

In accordance with the invention, FIGURES 1-3 illustrates the anchoring device in accordance with the invention enlarged to show the invention in detail generally at 10. The anchoring device 10 comprises an open helix 12 having a pointed insertion tip 14 at one end and an attachment head 15 at the other end.

Preferably, the anchoring device is comprised of a rigid, biocompatible material having a high-yield strength such as stainless steel or titanium. The device can also be made from a biodegradable material such as polyglycolic acid ("PGA"), polylactic acid ("PLA"), polydioxone hydroxy apatite ("PDA"), and the like. For example, the device 10 may be made from surgical-grade titanium or stainless steel wire having a wire diameter ranging from about 0.4 millimeters to about 3.0 millimeters, and more specifically from about 0.5 millimeters to about 2.0 millimeters, and most specifically from about 1.0 millimeters to about 2.0 millimeters. Optionally, the helix diameter may be of variable cross-section ranging from a smaller-diameter wire at the insertion tip to a larger-diameter wire near the attachment head 15.

The "slope" of the helix is used herein to mean the number of turns (i.e., one 360° rotation) per unit length and varies from about 0.5 turn per centimeter to about 10 turns per centimeter, and more specifically from about 0.5 turn to about 4 turns per centimeter, and most specifically from about 1 to about 2 turns per centimeter. The anchor generally comprises a length of helix sufficient to achieve from 0.75 to 4 complete 360° revolutions, or more specifically from about 1 to about 3 revolutions. Accordingly the length of the anchor for most general fastening or anchoring applications is from about 3 to about 18 millimeters, and more specifically from about 4 to about 15 millimeters, and most specifically from about 8 to about 15 millimeters. For plating or buttressing applications, the length of the anchor will generally

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range from about 5 to about 75 millimeters, preferably from about 5 to about 40 millimeters and most preferably from about 10 to about 20 millimeters.

The overall outer diameter of the open helix portion 12 of the anchoring device 10 ranges from about 1.5 to about 11 millimeters, and more specifically from about 3 to about 9 millimeters, and most specifically from about 5 to about 7 millimeters. The wire is generally circular in cross-section, although it is envisioned that it may be angular such as diamond-shaped or rhombohedral.

It is important that the anchor have an aspect ratio of from about 3 to about 5, preferably from 3.5 to 4.5, and most preferably around 4. As used herein, aspect ratio means the ratio of the helix outer diameter to the wire diameter. If the ratio is too large, the device is too rigid, whereas if the ratio is too small, the device is overly flexible.

The attachment head 15 of the anchoring device 10 may vary according to the specific application. For example, it may be desirable to include a broader compression area for direct attachment of connective or soft tissue to bone, as compared to suture techniques involving suturing or wiring the soft tissue in place with respect to the anchoring device. Examples of attachment heads suitable for suturing or wiring connective tissue include crossbars, hooks and eyelets.

FIGURE 1 illustrates an attachment head 15 having a crossbar 17 which arches slightly above the last helical turn and is attached such as by spot welding 18 at the terminal end. It may be further preferable to include an opening 19 or cannulation in the crossbar to allow for cannulated surgical techniques (i.e., placement of the anchor over a positioned wire which may be subsequently removed). The opening may range in size from 0.5 millimeters to 1.5 millimeters depending on the application.

The device and method of the invention are illustrated in FIGURES 3-5. In particular, FIGURE 4

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illustrates a section of bone generally at 20 having a cortex 22 and a cancellous portion 24. A pilot hole 25 has been drilled in the cortex 22 in order to ease insertion of the anchoring device 10. A countersink hole 26 through the cortex is also illustrated.

FIGURE 5 illustrates the anchoring device 10 as it has been partially implanted through the pilot hole 25 into the cancellous portion of the bone. In some instances where the cortex is particularly thin, a pilot hole may be unnecessary. The soft tissue is attached to the anchoring device when the device is in position such as by suturing or wiring to the attachment head 15 of the anchoring device 10.

FIGURES 6 and 7 illustrate an instrument which can be used for the implantation of the anchor in accordance with the present invention. Specifically, the instrument includes a central shaft 30 having a T-shaped handle 32 designed to allow the surgeon to easily grasp the handle 32 and rotate the shaft 30 to screw the anchor 10 into the bone through the optional pilot hole. The placement guide 34 includes a bottom surface 36 which can rest against the cortical surface where the anchor 10 is to be implanted. The guide 34 further includes an internal opening 38 having a diameter sufficient to receive the top portion of the anchor 10. The guide 34 further includes a bore 40 which provides a bearing surface for the shaft 30. At its lower end, the shaft 30 includes a head 42 having an internal slot 44 which receives the crossbar of the anchor 10 to enable the surgeon to apply torque to the anchor. The head 42 has an external diameter which cooperates with the internal diameter of the anchor 10. Optionally, the shaft 30 may also include a longitudinal, internal opening to receive a guide wire to allow for further cannulated surgical techniques.

During use of the anchor of the present invention, the attachment location is approached with standard surgical exposure. A pilot hole is drilled through the

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near cortex only and a drill sleeve is used to protect surrounding soft tissues. The anchoring device 10 is inserted with an insertion tool such that the attachment head 15 is left out of the bone. The angle of insertion
5 may be perpendicular to the bone surface or at a 45° angle. A suture may be passed under the exposed crossbar 17 of the attachment head 15 once or twice, depending on the surgeon's choice. The attachment tool is then used to countersink the attachment head 15 below bone level. The
10 ligament or tendon is then sutured into place with a preferred suturing method such as Bunnell, whip, or modified Kessler. The wound is subsequently closed and the procedure is completed in standard fashion.

FIGURES 8 and 9 show a second embodiment of the
15 anchor 80 having a modular head 82 attached to a helix 84. The helix 84 engages the bone as shown in the earlier embodiments. This version rotates through 540° ($1\frac{1}{2}$ full rotations) and terminates at one end in a three-sided point 86. At the other end, the helix 84 is formed into
20 a ring 88 to form a seat for the head 82. The ring 88 may be a complete circle or less than a circle, so long as it forms a good seat for the head 82. Preferably the ring 88 is the same diameter as the helix and the head 82 has the same outer diameter as the ring in order to allow the head
25 to be countersunk into a plate or bone.

Preferably both the head 82 and helix 84 are formed of implant-grade stainless steel (such as SS 22-13-5). The head 82 has a low, rounded, top profile, projecting from about 0.02 to 0.2 inch, and preferably from 0.05
30 to 0.1 inch from the top surface of the helix ring 88. The head 82 also includes an internal hex opening 90 to receive an anchor driver. The head 82 also includes a transverse through slot 92 shown in phantom in FIGURE 9. The slot can be used to hold sutures in order to anchor
35 tendons or ligaments. On the opposite side, the head 82 includes a necked area or stem 94 which is a constant

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diameter cylinder welded or otherwise adhered along the bottom edge to the ring 88.

EXAMPLE

5 Six samples of surgical-grade, stainless steel bone anchors in accordance with the invention were placed in a sample of artificial cancellous bone. Two samples each had a total longitudinal length of about 20 millimeters. The other four samples each had total lengths of
10 about 13 millimeters. The outer diameter of all samples was 5 millimeters and the wire diameter was 1.5 millimeters. Both long samples and two short samples had attachment heads which were crossbars and were attached by heliarc spot welding. The other short samples had cross-
15 bar attachment heads which were not welded.

 Pullout tests were conducted using an MTS instrument. Straight, longitudinal pull was applied to the embedded anchors; this reproduced the least favorable condition for pullout characteristics. The results are
20 shown in the table below. "Displacement" refers to bending of the crossbar in the longitudinal direction.

TABLE I
PLASTIC DEFORMATION

25

SHORT/NON-WELDED	SHORT/WELDED	LONG/WELDED
Average 48 lbs. with 2 millimeters of displacement	Average 52 lbs. with 2.2 millimeters of displacement	Average 58 lbs. with 2.4 millimeters of displacement

30

All of the numbers represent desirable anchoring values.

 While in accordance with the patent statutes the best mode and preferred embodiment has been set forth, the
35 scope of the invention is not limited thereto, but rather by the scope of the attached claims.

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WHAT IS CLAIMED IS:

1. An organic tissue anchor comprising a rigid, biocompatible, elongate member having a diameter of from about 0.4 millimeters to about 3 millimeters comprising surgical-grade titanium or stainless steel wire or a
5 bioabsorbable material which forms an open, helical structure having a length from about 3 millimeters to about 75 millimeters, an outer diameter of a constant dimension of from about 1.5 millimeters to about 15 millimeters, a slope from about .5 to about 10 turns per centimeter and
10 having at a first end an insertion tip and at a second end an attachment head which is capable of connecting organic tissue to said anchor and which comprises a crossbar having an eyelet for receiving a suture.

2. An anchor according to Claim 1, wherein the anchor is from about 2 to about 20 millimeters in length.

3. An anchor according to Claim 2, wherein the elongate member has a diameter of from about 0.5 to about
20 2 millimeters and a length of from about 4 to about 18 millimeters.

4. An anchor according to Claim 3, wherein the elongate member has a diameter of from about 1 to about 2
25 millimeters and a length of from about 8 to about 15 millimeters.

5. An anchor according to Claim 1, wherein said attachment head is a modular head which cooperates with
30 said open helical structure.

6. An anchor according to Claim 5, wherein said modular head includes an internal hex.

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7. An anchor according to Claim 3, wherein the helix achieves from about 0.5 to about 20 complete 360° revolutions.

5 8. An anchor according to Claim 7, wherein the anchor achieves from about 1 to about 4 revolutions.

10 9. An anchor according to Claim 2, wherein the overall outer diameter of the helix is from about 1.5 to about 11 millimeters.

10. An anchor according to Claim 1, wherein the attachment head is cannulated.

15 11. A method of securing tissue comprising:
accessing a surgical site including a tissue
anchoring site in bone;
implanting an anchor comprising an open, rigid,
biocompatible helix into said site, said helix being
20 formed from an elongate member having a circular cross-
section with a diameter of from about 0.2 to about 5
millimeters, and said helix having a length of from about
2 to about 75 millimeters, a slope from about 5 to about
10 turns per centimeter, and an outer diameter of from
25 about 1.5 to about 11 millimeters; and
attaching a tissue to said anchor.

30 12. A method according to Claim 11, wherein said step of attaching comprises suturing said tissue to said anchor.

35 13. A method according to Claim 11, including a step of making a pilot hole which is about the diameter of the elongate member in the bone prior to the insertion of the anchor in the bone.

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14. A method according to Claim 12, wherein said attaching step comprises suturing a ligament or tendon to said anchor.

5 15. A method of buttressing bone comprising the steps of:

accessing a surgical site including at least a first cortical bone surface aligning a plate having an aperture on said first cortical surface; and

10 implanting at least one anchor through said plate aperture into at least said first cortical surface, said anchor comprising an open helix having a length of from about 5 to about 75 millimeters, a slope of from about 0.5 to about 10 turns per centimeter, and said helix
15 being formed from an elongate member having a circular cross-section having a diameter of from about 0.2 to about 5 millimeters, said helix having a constant outer diameter, said helix further having at a first end an insertion tip and at a second end a head capable of applying a
20 compressive force in the direction of the first end.

25 16. A bone anchor comprising a rigid, biocompatible, elongate member comprising a wire having a regular, solid cross-section with a diameter of from about 1.0 millimeter to about 2 millimeters which forms an open, helical structure having a length from about 3 millimeters to about 75 millimeters, an outer diameter of a constant dimension of from about 3 millimeters to about 9 millimeters, a slope from about .5 to about 4 turns per centimeter, and an aspect ratio of about 3 to about 5, said
30 anchor having at a first end a bone insertion tip, and at a second end an attachment head having means for connecting organic tissue to said anchor, said attachment head being one piece with said helical structure, and said head having substantially the same outer diameter as said
35 helix.

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17. A bone anchor as set forth in Claim 16, wherein said attachment head is welded directly to said helical structure.

5 18. A method of buttressing bone comprising the steps of:

accessing a surgical site including at least a first cortical bone surface;

10 implanting at least one anchor into at least said first cortical surface, said anchor comprising an open helix having a length of from about 5 to about 75 millimeters, a slope of from about 0.5 to about 10 turns per centimeter, and said helix being formed from an elongate member having a circular cross-section having a
15 diameter of from about 0.2 to about 5 millimeters, said helix having a constant outer diameter, said helix further having at a first end an insertion tip and at a second end a head capable of applying a compressive force in the direction of the first end and wherein said head is
20 cannulated, and further including the steps of using a guide wire to achieve initial bone alignment and subsequently implanting said anchor about said guide wire by means of said cannulation.

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US

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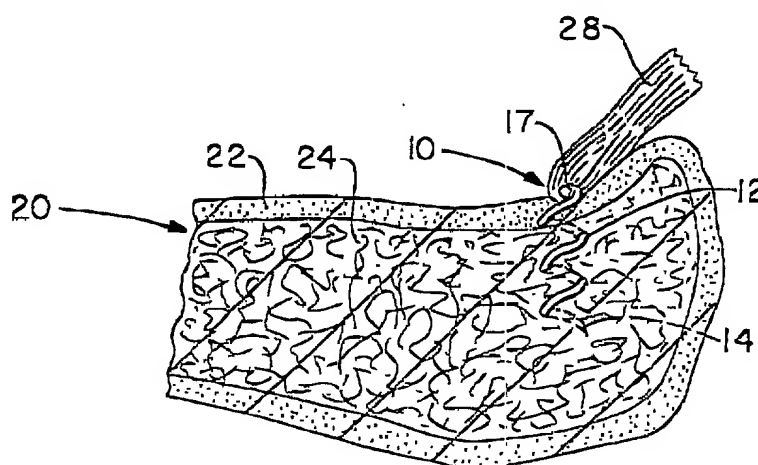
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Published

With international search report.

(54) Title: OPEN HELICAL ORGANIC TISSUE ANCHOR AND METHOD OF FACILITATING HEALING



(57) Abstract

The invention relates to a tissue anchor (10) which is an open helix (12) of biocompatible material having a slope of from 0.5 turns per centimeter to 10 turns per centimeter, a length from 3 mm to 75 mm, a diameter of from 1.5 mm to 11 mm, and an aspect ratio of from about 3 to about 5 to 1. The anchor can have a head (17) which is capable of securing or clamping tissue together, such as holding a suture in hole (19) to secure a ligament or tendon (28) to bone. The anchor can also have a head which causes an inward, compressive loading for use in fastening bone to bone, orthopedic plates to bone, or cartilage to bone.

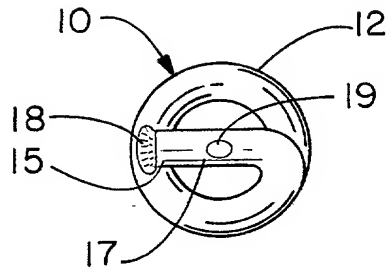


FIG. - 2

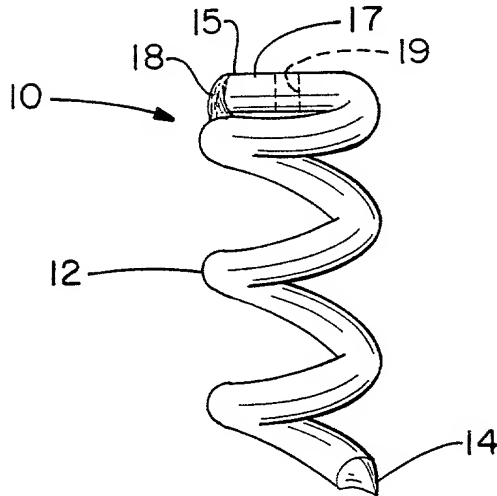


FIG. - 1

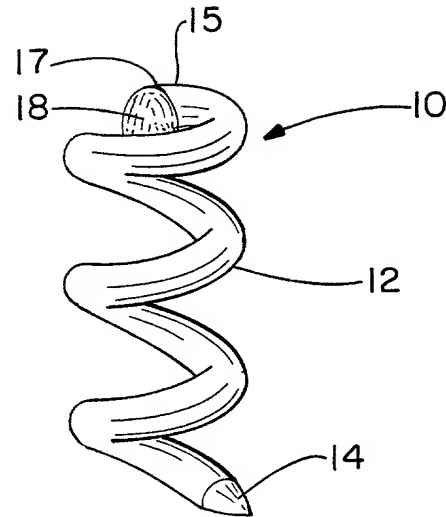


FIG. - 3

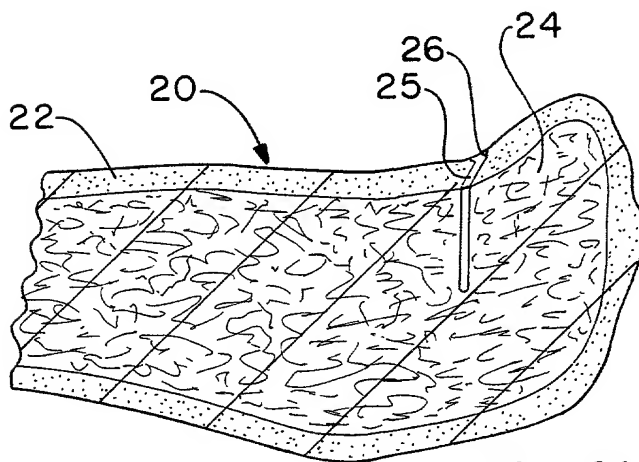
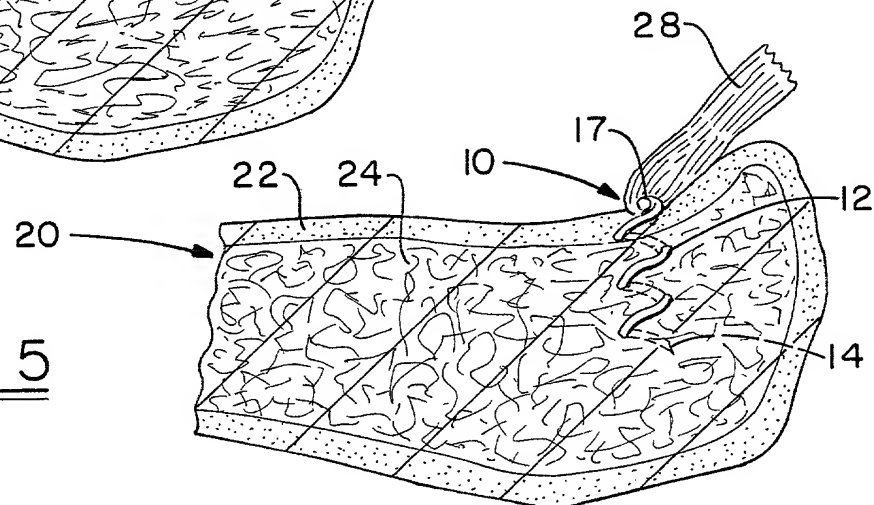


FIG. - 4

FIG. - 5



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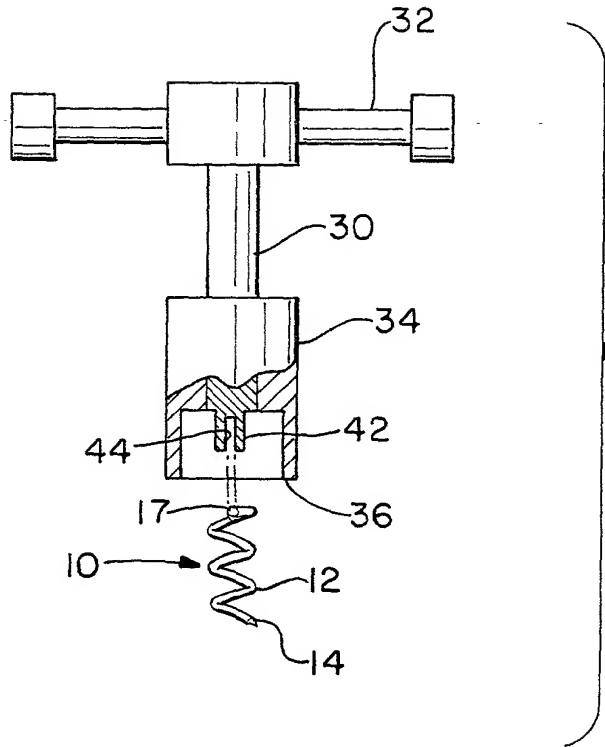


FIG. -6

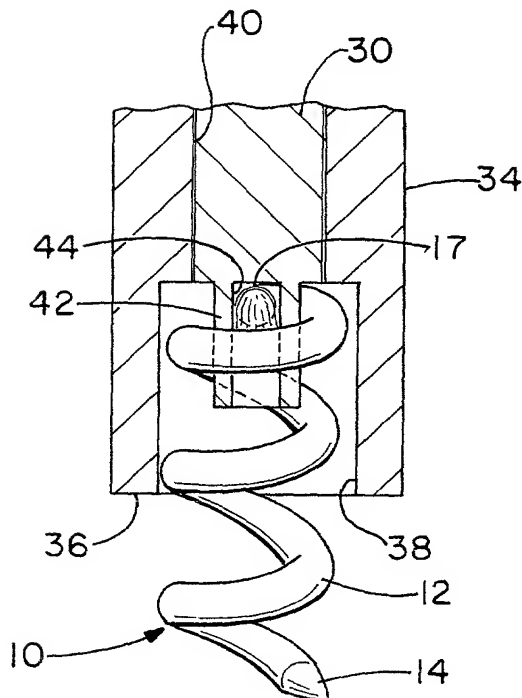


FIG. -7

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PTO/SB/01 (4-96)

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

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with Initial Filing

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Submitted after
Initial Filing

Attorney Docket Number ORTHOACIPCT.US

First Named Inventor KAY, DAVID B.

COMPLETE IF KNOWN

Application Number

Filing Date

Group Art Unit

Examiner Name

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

OPEN HELICAL ORGANIC TISSUE ANCHOR
AND METHOD OF FACILITATING HEALING

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY)

08/19/96

as United States Application Number or PCT International

Application Number

PCT/US96/13570

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(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code §119 (a)-(d) or §385(b) of any foreign application(s) for patent or inventor's certificate, or §365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

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				YES	NO
NONE			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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☐ Additional foreign application numbers are listed on a supplemental priority sheet attached hereto.

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DECLARATION

Page 2

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code §112. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
08/517,259		08/23/1995	

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority sheet attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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LAFERTY, Samuel B.	31,537		
ROTE, Frank C. Jr.	20,395		
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☐ Additional registered practitioner(s) named on a supplemental sheet attached hereto.


Direct all correspondence to:

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		Fax	330-535-1435
ZIP	44308-1133		

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

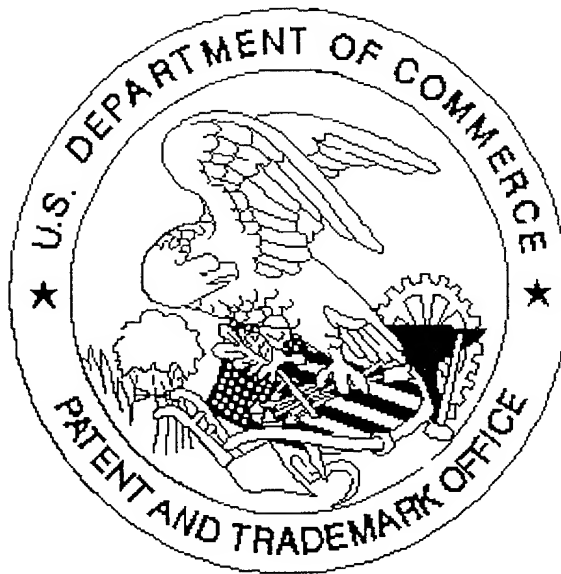
Name of Sole or First Inventor:

☐ A petition has been filed for this unsigned inventor

Given Name	DAVID	Middle Initial	B	Family Name	KAY	Suffix e.g. Jr.	
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